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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,012	04/13/2004	Micheal Patrick Dillon	R0130D-CON	4690

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EXAMINER

STOCKTON, LAURA

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 11/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/823,012	Applicant(s) DILLON ET AL.	
	Examiner Laura L. Stockton, Ph.D.	Art Unit 1626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2005.  
2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 48-62 is/are pending in the application.  
4a) Of the above claim(s) 53 and 55-62 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 48-52 and 54 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

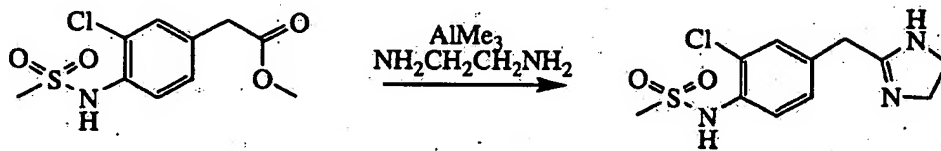
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**DETAILED ACTION**

Claims 48-62 are pending in the application.

***Election/Restrictions***

Applicants' election without traverse of Group I, and the species of Example 3 in step 4 on page 49 (reproduced below), in the reply filed on December 16, 2004 was acknowledged in the previous Office Action.

**Step 4**

The requirement was deemed proper and made FINAL in the previous Office Action.

Claims 53 and 55-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being

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drawn to nonelected inventions. Election was made **without** traverse in the reply filed on December 16, 2004.

Objections made in the previous Office Action that do not appear below have been overcome. Therefore, arguments pertaining to these objections will not be addressed.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application

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or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 48-52 and 54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 8, 10, 12-14, 18, 20, 27-30, 32, 44-47, 56-58, 60 and 64 of U.S. Patent No. 5,952,362 (Cournoyer et al.) and claims 1-10, 17 and 26-39 of U.S. Patent No. 6,756,395 (Dillon et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed compounds are generically described in the claims of U.S. Patent No. 6,756,395 and are positional isomers of the compounds claimed in U.S. Patent No. 5,952,362.

In U.S. Patent No. 6,756,395, see claim 1 (column 62) and especially the first compound listed in claim

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38 (column 65) of this patent which is the same as the first compound listed in instant claim 52.

In U.S. Patent No. 5,952,362, see claim 1 (columns 124-125) and especially claim 27 (column 127) and claim 44 (column 128). The sulfonamide group in the compounds found in U.S. Patent No. 5,952,362 is attached to the phenyl ring *meta* to the imidazolin-2-yl-methyl group instead of *para* to the imidazolin-2-yl-methyl group as instantly claimed (i.e., a positional isomer). Nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer, as claimed in U.S. Patent No. 5,952,362 since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. *In re Norris*, 84 USPQ 458 (1950).

One skilled in the art would thus be motivated to prepare compounds embraced by the claims of U.S. Patent No. 6,756,395, or alternatively, prepare positional

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isomers of the compounds claimed in U.S. Patent No. 5,952,362, to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial products which would be useful in treating, for example, urinary incontinence. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art.

### ***Response to Arguments***

Applicants' arguments filed October 20, 2005 have been considered. In regard to the obviousness-type double patenting rejection of the claims over U.S. Patent No. 6,756,395, Applicants state that a Terminal Disclaimer will be filed once all other outstanding claim rejections have been resolved.

In regard to the obviousness-type double patenting rejection of the claims over U.S. Patent No. 5,952,362, Applicants argue that: (1) very small differences in structure can drive different activities and discusses the structurally differences of non-related compounds

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and their various activities; (2) structurally related compounds do not necessarily share common properties; (3) the instant claimed compounds having a phenyl ring with a sulfonamide group attached *para* to the imidazolinylmethyl group have unexpectedly better properties than the corresponding *meta* compounds of U.S. Patent No. 5,952,362; and (4) the graphs found in the figures provided show that the greater increase in intraurethral pressure with respect to arterial blood pressure indicates good uroselectivity in the *para* compound.

All of Applicants arguments have been considered but have not been found persuasive. Applicants allege unexpected activity but have not persuasively demonstrated that the instant claimed compounds do in fact possess unexpected, beneficial and superior activity over the compounds disclosed and claimed in U.S. Patent No. 5,952,362. The showing Applicants provided was not persuasive because: (1) the showing



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and data were not submitted in a 1.132 Declaration; and (2) the activity being demonstrated, i.e. good uroselectivity, could not be found in the instant specification; and (3) the showing was not commensurate in scope of the instant claimed invention. Compare, for example, the structurally similar prior art compounds Nos. 1, 2, 5-7, 10, 20, 23 and 24 listed in the table in column 39, to the top of column 40, in U.S. Patent No. 5,952,362 and the instant compounds nos. 1-5 found in Table 1 on page 19 of the instant specification. In re Greenfield, 197 U.S.P.Q. 227 (1978) and In re Lindner, 173 U.S.P.Q. 356 (1972). Also see M.P.E.P. 716.02(d). The rejection is deemed proper and therefore maintained.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 48-52 and 54 are rejected under 35 U.S.C. 103(a) as being obvious over Cournoyer et al. {U.S. Pat. 5,952,362} for reasons set forth below.

The applied reference has a common inventor (i.e., Counde O'Yang) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this

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application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(1)(1) and § 706.02(1)(2).

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Claims 48-52 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cournoyer et al. {U.S. Pat. 5,952,362}.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Applicants claim imidazolin-2-yl-methylphenyl compounds. Cournoyer et al. teach imidazolin-2-yl-methylphenyl compounds that are structurally similar to the instant claimed compounds. See in Cournoyer et al., for example, formula 1 in columns 7 and 8 and especially the sixth compound listed in the table in column 39.

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between the compounds of Cournoyer et al. and the compounds instantly claimed is that the sulfonamide group is attached to the phenyl ring *meta* to the imidazolin-2-yl-methyl group instead of *para* to

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the imidazolin-2-yl-methyl group as instantly claimed (i.e., a positional isomer).

***Finding of prima facie obviousness--rational and motivation (MPEP***

***§2142-2413)***

Nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer, as taught by Cournoyer et al., since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. In re Norris, 84 USPQ 458 (1950).

One skilled in the art would thus be motivated to prepare positional isomers of the compounds taught by Cournoyer et al. to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial products which would be useful in treating, for example, urinary incontinence. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of *prima facie* obviousness has been established.

### ***Response to Arguments***

Applicants' arguments filed October 20, 2005 have been considered. Applicants argue that in view of the unexpected uroselectivity of the instantly claimed para compounds over the *meta* compounds disclosed by Cournoyer et al., Applicants believe that claims 48-52 and 54 are patentable over Cournoyer et al. In response, as stated above for the obviousness-type double patenting rejection, Applicants have not persuasively demonstrated that the instant claimed compounds have unexpected, beneficial and superior activity over the compounds of Cournoyer et al. Therefore, the rejection is maintained.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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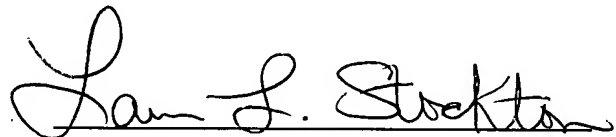
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, reading "Laura L. Stockton". The signature is fluid and cursive, with the first name "Laura" and last name "Stockton" clearly distinguishable.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

November 7, 2005